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Mindful attention training workshop for firefighters: Design and methodology of a pilot randomized clinical trial

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ABSTRACT

Mindfulness-based interventions have demonstrated efficacy with regard to diverse psychological symptoms across populations. Few studies have evaluated the efficacy of mindfulness-based interventions for firefighters. This pilot randomized clinical trial (RCT) is designed to determine the preliminary efficacy, feasibility, and acceptability of a novel mindfulness-based workshop (entitled "Healthy Action Zone Mindful Attention Training" [HAZMAT]) developed for firefighters (Clinical Trials Identifier: NCT04909216). An anticipated sample size of 100 firefighters from a large fire department in the southern U.S. will be recruited. Firefighters will be randomized to: (1) HAZMAT workshop or (2) waitlist comparison condition. Outcomes will be assessed at baseline and five follow-up time-points: post-workshop, 1-week follow-up, 1-month follow-up, 3-month follow-up, and 6-month follow-up. First, we will evaluate the acceptability of the HAZMAT workshop as defined by firefighters' self-reported satisfaction with the workshop. Feasibility will be defined by the proportion of firefighters who start and complete the full workshop. Second, we will examine the efficacy of the HAZMAT workshop, as compared to waitlist, on psychological symptom reduction, as defined by: self-reported symptom severity of PTSD, depression, anxiety, suicidal ideation, and alcohol use at each follow-up time-point. Third, we will evaluate the impact of the HAZMAT workshop, as compared to waitlist, on putative treatment targets, indexed via self-reported levels of (1) mindful attention and (2) nonjudgmental acceptance each follow-up time-point.

1. Introduction

Firefighters are repeatedly exposed to traumatic and stressful situations, increasing their vulnerability for the development of various psychological symptoms and disorders [1]. As a result of chronic stress and exposure to potentially traumatic events, as many as 32.4% of firefighters meet criteria for posttraumatic stress disorder (PTSD) with significantly more experiencing significant subclinical PTSD symptoms [2,3]. Approximately 22% of firefighters are also at risk for depression [4,5], 46.8% reported serious suicidal ideation, and 15.5% reported having made a suicide attempt during their firefighter tenure [6]. Alcohol use disorder (AUD) among firefighters is estimated at approximately 50% [7], nearly twice that of the general population [8]. Given the chronically stressful and potentially traumatic nature of the firefighting profession and the high rates of psychological disturbances among firefighters, the development of specialized mental health promotion and symptom prevention programs for this vulnerable

population is a priority.

Mindfulness, generally defined as bringing one's full attention to the present moment and taking a stance of nonjudgmental acceptance to the ongoing flow of sensations, thoughts, and/or emotional states [9-11], is a transdiagnostic factor with significant clinical relevance to the prevention and treatment of various psychological conditions. Among firefighters, research has demonstrated consistent negative associations between mindfulness and PTSD symptoms, depression symptoms, suicide ideation, and alcohol use problems [12,13]. Across populations, mindfulness-based interventions have demonstrated efficacy with regard to various psychological symptoms, including PTSD, depression, and alcohol use [14-16]. For example, among military veterans, mindfulness-based interventions have shown efficacy in targeting various aspects of psychological health, including PTSD, depression, and quality of life [17-25]. Further, mindfulness-based interventions, administered to military service members prior to combat stress training, have shown preliminary efficacy in reducing biomarkers of

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stress, compared to as-usual training [17].

Notably, few studies of mindfulness-based interventions focused on firefighters have been published. In a randomized clinical trial (RCT) of 121 firefighters, the Mindfulness-Based Attention Training (MBAT) program (n=42) was compared to a relaxation program (n=31) and to a no-training control condition (n=48) [26]. The MBAT was comprised of four 2-h sessions administered over the course of 4 weeks and focused on concentration, body awareness, opening monitoring, and connection. Firefighters randomized to the MBAT program reported significant increases in psychological resilience from pre-to post-workshop, as compared to the other conditions. In addition, those in the MBAT program showed increased positive affect and attentional task performance, and the MBAT condition reported more days of out-of-class mindfulness practice compared to the relaxation condition [26]. However, the RCT did not include a follow-up period to monitor the longitudinal outcomes of the program.

Two smaller-scale one-arm trials examined the utility of mindfulness-based resilience training programs for firefighters. First, a small-scale pilot study (N = 29) examined the effect of the Resilience@Work (RAW) Mindfulness Program on resilience, psychological flexibility, experiential avoidance, and cognitive fusion among firefighters [27]. The RAW Mindfulness Program was comprised of a 6-session, internet-based resilience training program focused on mindfulness training, psychoeducation, and a review of various skills and strategies derived from Acceptance and Commitment Therapy, Mindfulness-Based Stress Reduction, and Compassion-Focused Therapy [27]. Results suggested trends toward increased resilience and lower psychological inflexibility and experiential avoidance, as compared to baseline; no significant pre-to post-workshop differences were documented. This study did not include an RCT design or a control/comparison condition but provided evidence of feasibility of a digital mental health intervention for psychology well-being among firefighters [28]. Second, a small-scale pilot study (N = 31) evaluated the efficacy of a 2.5 day, compressed residential immersion format of Mindfulness-Based Resilience Training among first responders, including firefighters (22% of sample), with a booster session offered 30 days following the initial session [29]. Results indicated significant improvements in emotion regulation, occupational stress, fatigue, and emotional intelligence. Although first responders were followed for up to 90 days following the training, the study did not utilize an RCT design and no comparison condition was included [29]. These studies collectively underscore the need for larger-scale RCTs to evaluate the feasibility, utility, and efficacy of mindfulness-based interventions for the fire service.

Thus, the present investigation is a pilot RCT, formally entitled "Healthy Action Zone Mindful Attention Training" (HAZMAT), which aims to extend the literature by testing the efficacy of a one-session, 90min group mindful attention training program for firefighters, delivered via online video conference platform, on various mental health outcomes. Outcomes are assessed at baseline and five follow-up timepoints: post-workshop, 1-week follow-up, 1-month follow-up; 3-month follow-up; and 6-month follow-up. Specifically, the aims of the present investigation are three-fold. First, we will evaluate the acceptability of the HAZMAT workshop, as compared to waitlist, as defined by firefighters' self-reported satisfaction with the workshop (i.e., helpfulness, tolerability, relevance). Feasibility will be defined by the proportion of firefighters who start and complete the full workshop. Second, we will examine the efficacy of the HAZMAT workshop, as compared to a waitlist condition, on psychological symptom reduction among firefighters, as defined by: self-reported symptom severity of PTSD, depression, anxiety, suicidal ideation, and alcohol use at each follow-up time-point. Third, we will evaluate the impact of the HAZMAT workshop, as compared to waitlist comparison condition, on putative treatment targets, indexed via self-reported levels of (1) mindful attention and awareness and (2) nonjudgmental acceptance each follow-up timepoint. Finally, as secondary outcomes, we will examine firefighters' ratings of group dynamics and group cohesion within the HAZMAT workshop; and we will evaluate changes in occupational stress from baseline to 6-months post-workshop.

2. Materials and methods

2.1. Trial design overview

This pilot RCT is designed to determine the preliminary efficacy, feasibility, and acceptability of the novel mindfulness-based workshop specifically developed for firefighters (Clinical Trials Identifier: NCT04909216). An anticipated sample size of 100 firefighters from a large metropolitan fire department in the southern U.S. will be recruited. Firefighters will be randomized to: (1) HAZMAT workshop (i. e., "active" condition) or (2) waitlist comparison condition. Those randomized to the waitlist comparison condition will have the option of enrolling in the workshop after the end of the waitlist timeline (i.e., 6month follow-up). The 90-min, one session HAZMAT workshop will be conducted in an online video-conferencing group format. To examine changes in levels of mindfulness, mental health symptoms, and wellbeing over time, six online assessments will be administered: (1) baseline. (2) post-workshop. (3) 1-week post-workshop follow-up. (4) 1month post-workshop follow-up; (5) 3-month post-workshop followup; and (6) 6-month post-workshop follow-up. Please see Fig. 1 for an overview. The workshop will be administered by trained doctoral-level clinical and counseling psychology students, supervised by the principal investigator (PI) and supported by the fire service staff. All measures will be administered online and disseminated to each firefighter via confidential, unique email links.

2.2. Participant recruitment and eligibility

Participants will be 100 currently employed firefighters recruited from a large metropolitan fire department in the southern U.S. Inclusionary criteria will include: (1) current employment as career firefighter in the large metropolitan fire department and (2) being 18 years of age or older. Exclusionary criteria will be comprised of: (1) persons who are not actively employed in the fire department (e.g., former firefighters, retired firefighters), (2) persons with current (past month) suicidal or homicidal ideation with intent and plan (i.e., participants in imminent danger), and (3) persons who are unable or unwilling to provide verbal or written consent. Participants who endorse current (past month) suicidal ideation with intent and plan, assessed using the Beck Scale for Suicide Ideation - 5 (BSS-5) [30], will be contacted via phone by fire department staff psychologists within 24 h of their response and a suicide risk assessment will be conducted per empirical recommendations [31]. Fire department staff psychologists utilize department-specific resources to ensure immediate safety of the participant. The study was approved by all relevant institutional review boards, and all study procedures will be carried out in accordance with the Code of Ethics of the World Medical Association and Declaration of Helsinki.

2.3. Intervention and waitlist conditions

Participants randomized to the HAZMAT workshop condition will be scheduled following completion of the informed consent form and baseline questionnaire battery. The 90-min, online video-conferencing group workshop will include a 15-min break and will include up to 15 participants. The workshop will be led and facilitated by one to two doctoral clinical or counseling psychology students, all of whom are required to complete training in delivery of the workshop.

The HAZMAT workshop was developed by the authors in consultation with fire service psychologists and with direct input from fire-fighters to ensure compatibility with fire service culture (see Table 1). The workshop was tailored specifically to the fire service. For example, terminology was intentionally tailored to fire culture to enhance

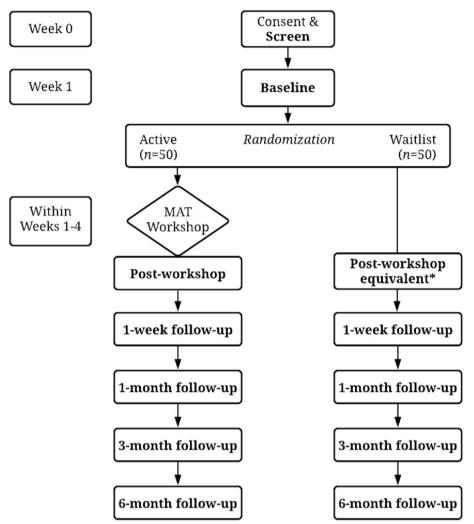


Fig. 1. CONSORT diagram. Assessments indicated in bold font. HAZMAT workshops were scheduled within 4 weeks of the baseline assessment. The postworkshop assessment is administered immediately following the HAZMAT workshop. *The postworkshop equivalent assessment includes identical measures as the post-workshop assessment for the HAZMAT condition but does not include measures assessing the workshop itself (i.e., Post-HAZMAT, GES, GCQ). Participants randomized to the waitlist condition are provided the option to participate in the HAZMAT workshop after completing the 6-month assessment.

relatability and rapport [32] as based on feedback from fire service personnel (e.g., 'workshop' versus 'therapy'; 'mindful attention training' versus 'mindfulness'; 'skillset' or 'toolbox' versus 'therapeutic strategies'). The HAZMAT workshop provides: (1) psychoeducation regarding common mental health concerns among firefighters, (2) introduction to the concept of mindful attention, its relevance to firefighters and first responders, generally, and examples of how mindful attention can prevent or decrease the severity of mental health symptoms, (3) introduction and in vivo practice of five experiential mindful attention training exercises (see Table 1), and (4) discussion of mindful attention exercises, their utility both on-and off-duty, and strategies to integrate mindful attention exercises in everyday life. Each mindful attention exercise is discussed in relation to the various facets of mindfulness (i.e., observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience) [9]. The in vivo exercises are practiced by the participants and facilitators during the workshop session (see Table 1). These exercises are derived from techniques commonly administered across various mindfulness-based interventions [10,11,33, 34]. Workshop facilitators introduce mindful attention exercises and firefighters will practice each exercise in vivo during the workshop, engage in discussion about their experiences, and provide feedback regarding the utility of the exercise for them personally and for firefighters, generally.

Participants randomized to the waitlist comparison condition will not attend the workshop. Instead, waitlist participants will follow an identical assessment schedule to 'active' condition participants to

account for time-varying factors in symptom severity. Participants in the waitlist condition will be given the option to participate in the HAZMAT workshop at the conclusion of the 6-month follow-up assessment.

2.4. Intervention fidelity

Workshop facilitators are doctoral students in clinical or counseling psychology. All facilitators will receive direct training in the HAZMAT workshop. Specifically, training is conducted by the PI and manual development team and includes 2–3 h of manual review in addition to 2 h of role plays of workshop material. Continued training and group supervision for the HAZMAT workshop will be provided by the PI, a licensed clinical psychologist, on a biweekly basis through the course of the trial. Workshop-related issues will be discussed in group supervision meetings and continued role plays will be conducted within supervision for the duration of the trial on an as-needed basis. Workshops will not be recorded for adherence review purposes given the preliminary nature of the trial. Intervention adherence checklists, based upon manual content, were developed for facilitators to complete before, during, and after HAZMAT workshops.

2.5. Measures

2.5.1. Screening and eligibility

A brief, online questionnaire will be administered to potential participants to determine study eligibility. Questions will include the

Table 1
Health action zone mindful attention training (HAZMAT) workshop: Content summary.

Topic	Objective	Intervention Content
Firefighter Mental Wellness	Psychoeducation	Discussion of stressors and mental health difficulties firefighters may experience
Mindful Attention Training	Psychoeducation	Defining mindful attention facets; how it can decrease or buffer severity of
	In vivo practice and discussion	it can decrease or butter severity of various mental health symptoms Mindful Breathing Exercise "During the exercise, just notice how you feel in your mind and in your body. You can complete the exercise with your eyes closed or keep them open and try to focus on an object." Body Scan Meditation "A body scan meditation is one type of mindfulness exercise which promotes greater awareness of the physical body. It uses physical sensations and visualization as an anchor to root the mind in the physical body and in the present moment. The video will instruct you to focus on various parts of your body (e.g., legs, arms, neck), which is different from the previous exercise which focused on your breathing." Bell Exercise "A helpful exercise to engage in observing is to use a repetitive, complex sound, such as a bell, to focus our senses on the present moment. The following recording contains the sound of a Tibetan singing bowl being repeatedly struck with a soft mallet. This calming sound is a wonderful focal point for meditation. Simply absorb your attention in the sound of the mindfulness bell. No mantra is required, no special
		breathing techniques are needed, just let your awareness be consumed by the sound of the bell." Internal Surveillance Exercise "When we begin this exercise, we are simply scanning through our mind and body and assessing what we feel like right
		now. What is my energy like? Concentration? Any tightness anywhere? Pain? Emotions that are overwhelming me? It is important to keep in mind that this isn't meant to be a judgement process. It's merely observing the waves come and go as if you are sitting on a beach watching wave after wave crash into shore." Feelings Wheel Exercise
		"The Feelings Wheel can help us put words to emotions and care for our mental health. You can scan the wheel to discover what adjective best describes your state and then allow that understanding to empower how you want to meet the moment."
	Skills Application	Utility of practicing mindful attention on- and off-duty; how to integrate it into daily life

Note. Each $in\ vivo$ practice was followed by a brief discussion. The duration of each exercise is approximately 3–5 min.

assessment of current employment status with the fire department as a first responder and age confirmation (age 18 or older). Eligible participants will then be asked to provide contact information to facilitate online data collection and workshop scheduling, pending randomization to the active intervention condition.

2.5.2. Acceptability outcomes

The Post-HAZMAT Workshop Questionnaire (Post-HAZMAT) is a 10-

item, self-report questionnaire developed by the PI to assess the degree to which participants found the workshop helpful, tolerable, and relevant to firefighters, generally. Examples of some of the statements included: "The workshop was useful", "The workshop will be helpful for other firefighters," and "I felt comfortable in the workshop." Participants will be asked to rate each statement on a 10-point Likert scale from (0 = $Strong\ disagree\ to\ 10 = Strong\ dy\ agree$). Items will be summed to produce a workshop acceptability variable that will be examined as an outcome variable. Acceptability will be defined as a mean score of 5 or higher.

2.5.3. Primary psychological symptom outcomes

The *Life Events Checklist for DSM-5 (LEC-5)* [35] is a 17-item self-report measure designed to screen for potentially traumatic events in a respondent's lifetime. Participants are asked to indicate whether they were exposed to any of the 16 potentially traumatic events listed. Exposure to a potentially traumatic event type will be coded as 'positive' if participants indicated the event happened to them, they witnessed it, or if it was part of their job. The total number of positive exposure event types will be summed to produce an overall trauma load (i.e., number of potentially traumatic event types) variable, which will be evaluated as a covariate.

The Posttraumatic Stress Disorder Checklist for the DSM-5 (PCL-5) [36] is a 20-item self-report measure that assesses the severity of DSM-5 PTSD symptoms over a specific timeframe using a 5-point Likert scale (0 = Not at all to 4 = Extremely) (timeframe varies based on assessment time-point, see Table 2). Participants will be instructed to complete the PCL-5 with reference to the "worst" traumatic event endorsed. The PCL-5 employs to examine the presence and severity of DSM-5 PTSD symptoms, with higher total scores indicating elevated symptom severity. The PCL-5 total score will be evaluated as an outcome variable in this study.

The Overall Depression Severity and Impairment Scale (ODSIS) [37] is a 5-item self-report measure that assesses past-week depression-related symptoms, particularly symptom severity and functional impairment. Items are rated on a 5-point Likert scale (0–4), with higher scoring indicating greater severity of depressive symptoms. In the current study, the total score of the ODSIS will be evaluated as an outcome variable.

The Overall Anxiety Severity and Impairment Scale (OASIS) [38] is 5-item self-report measure assessing for past week anxiety-related symptoms, with an emphasis on symptom severity and functional impairment. Items are rated on a 5-point Likert scale (0–4), with higher scoring indicating greater severity of anxiety symptoms. The OASIS total score will be employed as an outcome variable in the present study.

The *Beck Scale for Suicide Ideation – 5 (BSS-5)* [30] is a 5-item self-report measure, derived from the long form version of the *BSS* (i.e., first five items of the BSS), designed to identify individuals at risk for suicide by assessing the intensity of past-week suicide ideation or desire. Higher total scores on the BSS-5 indicate more severe suicide ideation. The BSS-5 has demonstrated strong psychometric properties [39,40]. In the current study, the BSS-5 total score will be evaluated as an outcome variable.

The Alcohol Use Disorders Identification Test (AUDIT) [41] is a 10-item self-report measure that assesses alcohol-related problems and alcohol consumption over a specific timeframe (timeframe varies based on assessment time-point, see Table 2). Higher scores on the AUDIT reflect greater problematic alcohol use, with scores ranging from 0 to 40. The AUDIT total score will be evaluated as an outcome variable. All participants will be screened with the full AUDIT at baseline and at the 6-month follow-up. The first three items of the AUDIT (i.e., AUDIT-C [42]) will be administered at follow-ups to evaluate hazardous alcohol use over time, consistent with past work [43].

2.5.4. Mindfulness outcomes

The Five Facet Mindfulness Questionnaire (FFMQ) [9] is a 39-item measure that assesses five mindfulness facets: observing (i.e., attention to internal and external experiences), describing (i.e., ability to label

 Table 2

 Summary of measures and assessment time-points.

Measure	Screen	Baseline	Post-workshop	1-week	1-month	3-month	6-month
Demographics, Medical Information, and Firefighter Service History		X					
Five Facet Mindfulness Questionnaire (FFMQ)		X		X	X	X	X
Mindful Attention Awareness Scale (MAAS)		X		X	X	X	X
Life Events Checklist for DSM-5 (LEC-5)		X					
Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5)		X	X	X	X	X	X
Overall Depression Severity and Impairment Scale (ODSIS)		X	X	X	X	X	X
Overall Anxiety Severity and Impairment Scale (OASIS)		X	X	X	X	X	X
Sources of Occupational Stress (SOOS)		X					X
Beck Scale for Suicide Ideation - 5 (BSS-5)		X	X	X	X	X	X
Alcohol Use Disorders Identification Test (AUDIT; AUDIT-C)		X	X	X	X	X	X
Post-HAZMAT Workshop Questionnaire*			X				
Group Evaluation Scale (GES)*			X				
Group Cohesion Questionnaire (GCQ)*			X				

Note. *Denotes questionnaires not included in post-workshop assessment for participants randomized to the waitlist condition. FFMQ [9]; MAAS [44]; LEC-5 [64]; PCL-5 [65]; ODSIS [66]; BSS-5 [30]; AUDIT [67]; Post-HAZMAT Workshop Questionnaire (developed by study team); GES [45]; GCQ [46].

internal experiences), acting with awareness (i.e., attention to activities in the moment), non-judging of inner experience (i.e., ability to remain non-evaluative about internal experiences), and non-reactivity to inner experience (i.e., ability to allow internal experiences to come and go) [9]. Items are rated on a 5-point Likert-type scale ($1 = Never \ or \ very \ rarely true$ to $5 = Very \ often \ or \ always \ true$) and specific items are reversed scored (e.g., a score of 5 is reversed to a 1). In the current study, the average score of the FFMQ (i.e., the average rating by a participant across all items) as well as the average score of each facet will be evaluated as mediators as well as outcome variables.

The *Mindful Attention Awareness Scale (MAAS)* [44] is a 15-item self-report scale assessing an individual's capacity for mindful attention and their level of dispositional mindfulness. Items are rated on a 6-point Likert-type scale ($1 = Almost\ always\ to\ 6 = Almost\ never$), with higher total scores indicating greater levels of dispositional mindfulness. The total score of the MAAS will be evaluated as a mediator as well as an outcome variable in the current study.

2.5.5. Secondary outcomes

The *Group Evaluation Scale (GES)* [45] is a 7-item, self-report measure assessing how the participant felt while participating in the group, particularly level of comfort and sense of being understood by other group members. Statements (e.g., "Within the group I felt well understood") are rated using a 7-point Likert scale (1–7; anchors vary by item), with higher scores indicating favorable group evaluations. Items will be summed to produce a group evaluation score that will be employed as a secondary outcome variable; higher scores indicate greater favorability. Mean scores of 4 or greater will define acceptable levels of group dynamics.

The *Group Cohesion Questionnaire (GCQ)* [46] is 12-item, self-report measure assessing a participant's view of the cohesion of the group and the quality of the group dynamic. Statements (e.g., "Group members appeared tense and anxious" [reverse scored]) are rated using a 7-point Likert scale (0 = Not at all to 7 = Extremely), with higher scores indicating favorable views of the group cohesion and dynamic. Items will be summed to produce a group cohesion score that will be employed as a secondary outcome variable; higher scores indicate greater group cohesion. Mean scores of 4 or greater will define acceptable levels of group cohesion.

The Sources of Occupational Stress (SOOS-14) [47] is 14-item self-report measure used to assess levels of occupational stress (i.e., harmful physical and psychological responses that occur when job requirements do not align with the worker's abilities, resources, and/or needs) among firefighters. The SOOS-14 total score, assessing overall levels of occupational stress, will be evaluated as a secondary outcome in the current study.

2.6. Procedures

The study is registered on clinicaltrials.gov (Clinical Trials Identifier: NCT04909216). The study is actively recruiting participants. All study procedures are remotely administered in response to the COVID-19 pandemic and to increase the dissemination and implementation potential of this workshop, pending demonstration of acceptability, feasibility, and preliminary efficacy. The trial is comprised of a total of 6 time-points: an online baseline assessment, one virtual workshop and a series of follow-up assessments (i.e., post-workshop [administered immediately following workshop, at same time-point], 1-week, 1-month, 3-month, and 6-month). Participants in each condition (i.e., workshop versus waitlist control) will receive the same set of online questionnaires at every time-point (see Table 2). Additionally, all participants will be compensated with a \$10 e-gift card after completing each assessment and will receive a \$25 e-gift card after completing the 6-month follow-up assessment.

Interested firefighters will receive regular recruitment emails via the fire department monthly email lists; study flyers will be posted throughout the department. In addition, fire service psychologists will alert firefighters of the study opportunity. Individuals interested in participating in the study will be provided access with a link to electronically sign a consent form. After consenting, individuals will be asked to complete eligibility questions (i.e., "Are you currently employed as a first responder?" and "Are you 18 years of age or older?"). Eligible participants will then be routed to complete the rest of the survey at a time and place of their choosing. Participants will be able discontinue participation at any time without penalty.

Participants randomized to the 'active' condition (n = 50) will be scheduled for the HAZMAT workshop and will complete a brief, online post-workshop assessment at the conclusion of the workshop. Participants who are randomized to the waitlist comparison condition (n = 50) will follow the same timeline for assessments as those randomized to receive the HAZMAT workshop but will not participate in the workshop. Accordingly, waitlist participants will be provided the opportunity to participate in the HAZMAT workshop after completing the 6-month follow-up assessment. Of note, participants who miss a specific timepoint will still be contacted (i.e., via email, text, and/or phone, depending on the contact information and consent for contact provided by each participant) with reminders to complete the assessment for the next time-point. Each workshop will occur within 4 weeks of completing the baseline assessment. We anticipate an attrition rate of 20% at study follow-up assessments [48], and as such, we will recruit 120 participants in order to obtain at least 100 participants who complete all study time-points.

2.7. Statistical analysis plan

The primary objective of this pilot RCT is to examine the effects of the HAZMAT workshop on improving mindfulness and reducing the severity of mental health correlates over time, including self-reported symptom severity of PTSD (for trauma-exposed participants), depression, suicidal ideation, and alcohol use, compared to the waitlist control condition. Randomization to intervention condition will be conducted using a simple randomization design, given the proposed sample size and scope of this pilot RCT [49]. Accordingly, allocation concealment will be utilized to prevent selection bias during recruitment.

Data will first be examined for multivariate normality; the maximum likelihood (ML) estimator will be used if data are approximately normal, and robust maximum likelihood will be used if the data are not multivariate normal. Categorical outcomes (e.g., hazardous drinking status, derived from the AUDIT) will be estimated using the mean and variance adjusted weighted least squares estimator when appropriate. Although we anticipate minimal attrition at follow-up assessments (<20%), missing data will be evaluated using Little's Missing Completely At Random (MCAR) test. Missing data will be handled using direct ML techniques within MPlus [50] and a missing at random assumption [51] will be applied as relevant. The equivalence of the random assignment of groups regarding key baseline characteristics will be assessed. Should groups differ on any characteristics, we will conduct analyses both with and without these variables as covariates to determine whether any potential randomization failures might impact results. Latent growth models (LGM) will be used to model linear trajectories of change in outcomes. Evaluation of LGM model fit will be examined using fit diagnostics (i.e., standardized residuals) and fit statistics (i.e., root mean square error of approximation) following recommended cutoffs [52]. To better understand the potential reproducibility of our findings, conclusions will be based on both statistical significance and magnitude of associated effect sizes.

Based on past research among firefighter populations, it is hypothesized that the HAZMAT workshop will evince small-to-moderate effects on post-workshop and follow-up outcomes. Extant sample size guidelines for pilot RCTs were utilized to identify the target sample size necessary to detect effects and increase the likelihood of appropriate power for the future main trial [53]. For a pilot RCT design, current guidelines [53] indicate that the targeted sample size of 100 participants would yield 90% power to detect small to moderate effects for study aims at alpha = .05. As such, the target sample size is well above current guidelines and the "rule of 12" recommendation (e.g., 12 participants per arm) for pilot studies in clinical research [54]. Accordingly, there will be a particular emphasis on effect sizes and confidence intervals throughout data analysis to maximize replicability and inform future work.

3. Discussion

This pilot RCT will provide evidence of feasibility, acceptability, and efficacy of a mindfulness-based mental health promotion and symptom prevention intervention for firefighters. The outcomes of this study will provide essential data to support larger multi-site project proposals. This line of inquiry has potential to inform national dissemination and implementation efforts for mental health services in the fire service.

This RCT has potential to meaningfully contribute to the nascent but growing literature on the efficacy of mindfulness-based interventions for first responders broadly [55–60] and firefighters, specifically. Given demonstrated efficacy of mindfulness-based interventions for various psychological conditions [14–16], this trial builds on a large body of work and extends it to the understudied, chronically trauma-exposed population of firefighters. Among a sample of 100 firefighters, the trial will examine the efficacy of the HAZMAT workshop, as compared to a waitlist condition, on psychological symptom reduction, feasibility and acceptability, and impact on putative treatment targets (i.e.,

mindful attention and awareness, nonjudgmental acceptance). The program will be delivered virtually, via online video conference, in group format and in the context of one 90-min session, enhancing potential for dissemination and implementation pending evidence of preliminary efficacy. The study includes an RCT design and assessments administered across six time-points, addressing the limitations of past work on testing mindfulness-based interventions among firefighters [26, 27].

While the HAZMAT workshop is comprised of only one-session, one-session resilience training workshops among firefighters have demonstrated efficacy in resilience-building and symptom prevention [61]. For example, the Disaster Working Resiliency Training Program (DWRT) is a 4-h single session workshop, developed for disaster workers, including firefighters. In the context of an RCT, disaster workers randomized to the DWRT program, compared to a waitlist condition, showed improvements in healthy lifestyle behaviors, spiritual growth, and stress management at 3-month post-workshop follow-up. Notably, of those who experienced a traumatic event during the period between post-workshop and the 3-month follow-up), workers in the waitlist condition, compared to DWRT, were more likely to report increases in perceived stress, PTSD, and depression symptoms [61]. This trial is notable as it documented the efficacy of a single-session workshop in preventing psychopathology in addition to enhancing resilience.

Study limitations are worthy of note. First, given that this study is a pilot RCT, recruitment will focus on firefighters from one large urban fire department, wherein all firefighters are career responders who conduct fire suppression and EMS services. Should the HAZMAT workshop demonstrate preliminary efficacy, future studies might extend this work to geographically diverse firefighters (e.g., suburban, rural) and volunteer firefighters, given emergent studies suggesting that volunteer firefighters may report greater mental health symptoms compared to career firefighters [62,63]. Second, the study relies on self-report assessments of symptoms administered in an online format to facilitate recruitment and retention for purposes of the pilot RCT. Future work might include interview-based and experimental measures in the context of RCTs to improve the generalizability of findings with more rigorously assessed symptomatology and mechanisms of change. Third, given the preliminary nature of the trial, HAZMAT workshops will not be recorded. Pending evidence of initial feasibility and efficacy, future trials should incorporate more rigorous fidelity monitoring procedures. Fourth, the study did not specifically select firefighters on the basis of psychiatric symptoms, trauma exposure, or years of service, as it was intended to test feasibility and efficacy across various symptoms. Future work targeting specific facets of the fire service (e.g., new academy recruits) or firefighters who have experienced potentially traumatic events or who report clinically significant symptoms will be important. Relatedly, this study does not assess exposure to potentially traumatic events during the follow-up period as the sample size is underpowered for tests of moderation and the focus of this pilot RCT is to test preliminary acceptability, feasibility, and efficacy in targeting outcomes of interest. Nevertheless, it is possible that stress and trauma exposure experiencing during the study may affect outcomes, and future work should integrate assessment of stress and trauma throughout the study timeline in larger samples powered for tests of moderation; firefighters are a population with potentially chronic occupational stress and trauma exposure.

In summary, this pilot RCT examines the effect of a novel mindfulness-based intervention, the HAZMAT workshop, on behavioral health outcomes in firefighters. The results will build upon the preliminary evidence for the efficacy of mindfulness-based interventions for firefighters [26], specifically, and first responders [55–60], broadly, and extend a well-established literature on the efficacy of mindfulness-based interventions among military and veteran personnel and populations meeting criteria for various types of psychological symptoms and conditions [17–25]. This work has clinical import and potential to inform policy, if feasibility and preliminary efficacy is established.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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